

Decision Memo for Neuromuscular Electrical Stimulation (NMES) for Spinal Cord Injury (CAG-00153R)

Decision Summary

One type of NMES that is used to enhance functional activity of spinal cord injured (SCI) patients is commonly referred to as functional electrical stimulation (FES). These devices use electrical impulses to activate paralyzed or weak muscles in precise sequence and have been utilized to provide SCI patients with the ability to walk. Based on all of the evidence that we have reviewed, it is our intention to issue a positive national coverage determination for the use of NMES/FES limited to walking in SCI patients, but we will maintain the existing national non-coverage policy for the treatment of disuse atrophy in SCI patients. Use of NMES/FES poses a risk from falling for SCI patients. It also requires that a person possess certain abilities to successfully use these types of devices. In addition, patients require many sessions of physical therapy to learn how to use the device properly and the clinical studies report that many patients do not use NMES/FES long term. Therefore, we will cover an NMES/FES system when used by an SCI patient for walking in the home only after the patient has completed regular sessions of physical therapy with the device over a period of 3 months. This trial period of physical therapy will enable the clinician to properly evaluate the person's ability to use these devices for the long term.

The goal of this therapy must be to train SCI patients on the use of NMES/FES devices to achieve walking, not to reverse or retard muscle atrophy. The training program would be covered under the physician fee schedule, with no additional payment being made for the equipment used by the patient, as the equipment is in the practice expense portion of the payment.

Consistent with the FDA labeling for Parastep®I and the inclusion criteria for most of the studies reviewed, coverage for NMES/FES for walking, whether in the setting of physical therapy or home use, will be limited to SCI patients with all of the following characteristics:

- 1) persons with intact lower motor units (L1 and below);
- 2) persons with muscle and joint stability for weight bearing at upper and lower extremities that can demonstrate balance and control to maintain an upright support posture independently;
- 3) persons that demonstrate brisk muscle contraction to NMES and have sensory perception of electrical stimulation sufficient for muscle contraction;

4) persons that possess high motivation, commitment and cognitive ability to use such devices for walking;

5) persons that can transfer independently and can demonstrate standing tolerance for at least 3 minutes;

6) persons that can demonstrate hand and finger function to manipulate controls;

7) persons with at least 6-month post recovery spinal cord injury and restorative surgery;

8) persons without hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis; and

9) persons who have demonstrated a willingness to use the device long-term.

NMES/FES for walking will not be covered in SCI patients with any of the following:

- 1) persons with cardiac pacemakers;
- 2) severe scoliosis or severe osteoporosis;
- 3) skin disease or cancer at area of stimulation;
- 4) irreversible contracture; or
- 5) autonomic dysreflexia.

All uses of NMES other than for the treatment of disuse atrophy in neurologically intact patients and for walking in SCI patients remain non-covered.

Decision Memo

TO: File: Neuromuscular electrical stimulation (NMES) for use by spinal cord injured (SCI) patients for standing and walking

FROM:

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RE: Coverage Decision Memorandum for Neuromuscular Electrical Stimulation for Spinal Cord Injured Patients

DATE: July 22, 2002

This memorandum serves four purposes: (1) outlines the description of neuromuscular electrical stimulation (NMES) for spinal cord injured patients; (2) reviews the history of Medicare's coverage policies on neuromuscular electrical stimulation; (3) presents and analyzes the relevant clinical and scientific data related to the use of neuromuscular electrical stimulation for spinal cord injured patients; and (4) delineates the rationale for our decision to revise our current non-coverage policy for the use of NMES for walking in spinal cord injured patients.

Clinical Background

Spinal Cord Injury

It is estimated that the prevalence of spinal cord injury (SCI) is approximately 40 cases per million, with an incidence of 11,000 new cases each year. Fifty-five percent of spinal cord injuries occur in persons between the ages of 16 to 30 years old. Overall, approximately 80% of all SCI patients are male, with motor vehicle accidents accounting for 40% of cases, violent acts another 25% and falls 20%, with sports injuries and miscellaneous reasons accounting for the remaining 15%. [1](#)

The spinal cord and the brain together make up the central nervous system. The peripheral nervous system connects the central nervous system with sensory organs, other organs, muscles, blood vessels and glands. The peripheral nervous system courses through the limbs, torso and other body parts.

The spinal cord is a complex neural structure containing, neurons, long fibers called axons, and dendrites. Axons carry signals from neurons. The spinal cord is arranged in segments along its length, with higher segments important for movement and sensation in the upper parts of the body and lower segments important for the lower parts of the body.[2](#) Nerves emanating from each spinal cord segment connect to specific structures of the body. The segments in the neck, or cervical region (C1-C8), relay neural signals to and from the neck, arms, and hands. Those in the thoracic, or upper back region (T1-T12), relay signals to and from the torso and some parts of the arms. Those in the upper lumbar, or mid-back region (L1-L5), relay signals to and from the hips and legs. The sacral segments (S1-S5) relay signals to and from the groin, and some parts of the lower extremities. Persons with quadriplegia (weakness of all four limbs) have sustained injuries to at least one of the eight cervical segments of the spinal cord and those with paraplegia (weakness of the lower extremities) have lesions in regions of the spinal cord below the cervical level.

An injury to the spinal cord damages cells within the spinal cord or severs the nerve tracts that relay signals up and down the spinal cord. The common types of injuries are contusion or bruising of the spinal cord, compression caused by pressure on the spinal cord, or lacerations which are severing or tearing of nerve fibers. The types of disability associated with spinal cord injury depend upon the type, severity and location of the injury, and SCI is referred to as being either complete or incomplete, depending upon the severity of injury. The destruction of nerve fibers that carry motor signals from the brain to muscles leads to muscle paralysis. Destruction of sensory nerve fibers can lead to loss of sensation, such as touch, pressure and temperature.

Neuromuscular Electrical Stimulation

There are two broad categories of NMES. One type stimulates the muscle when the patient is in a resting state to treat patients with muscle atrophy. A second type is used to enhance functional activity in neurologically impaired patients. These devices use electrical impulses to activate paralyzed or weak muscles in precise sequence and have been utilized to provide SCI patients with the ability to walk. This technology is utilized for both upper extremity (e.g., improved hand grasp function) and lower extremity rehabilitation, but the current decision memorandum is focused upon a very specific lower extremity application, to enhance standing and walking. NMES used for this indication is also commonly called functional electrical stimulation (or FES). NMES is used to assist standing and ambulation in paraplegics or quadriplegics who have adequate use of their upper extremities to allow balancing with a walker (or with elbow-support crutches), assuming satisfactory pulmonary and cardiovascular functioning. However, this technology is not intended to replace the wheelchair, which still remains the main source of transportation.

The first use of NMES to enhance lower extremity functions in paraplegics began with work on the correction of foot-drop³. The use of surface stimulation to assist standing and walking for persons with complete and incomplete spinal cord injury began in the 1970's. Two surface electrodes per leg were used to stimulate standing and reciprocal walking by direct activation of the quadriceps muscles.

There are three types of NMES: Transcutaneous (surface), percutaneous, and subcutaneous (fully implanted) systems. One such transcutaneous device is the Parastep®I system which is non-invasive and uses a microcomputer microchip that synchronizes stimulation at various sites. Surface or transcutaneous devices send electric current through the skin. Generally four electrodes are placed on the skin and current crosses through the skin to stimulate the appropriate muscles. The Parastep®I system generates trains of pulses to trigger action potentials of selected nerves at the quadriceps for knee extension, at the common peroneal nerve for the hip flexion withdrawal reflex and the paraspinal muscles/gluteus maximus muscle for enhancing trunk stability. Most patients use a walker for balancing support.⁴ This device has received FDA approval to enable standing and walking.

Another surface system is the hybrid body-brace system, which is a body brace/NMES combination.⁵ This system combines an orthosis with NMES. These systems are designed for standing and ambulation of SCI patients who have full use of their upper extremities so they can balance themselves by using a walker or crutches. The NMES components consist of a four-channel surface stimulator and surface electrodes placed over the rectus femoris and hamstrings.

Benefits of a surface system are that they are noninvasive with relative ease in placing and removing electrodes. The disadvantages of this type of system are 1) the inability to maintain isolated muscle selectivity; 2) difficulty in stimulating deeper muscles; 3) poor reproducibility of contraction due to variability in electrode placement; 4) inconvenience in placing multiple electrodes; 5) pain from stimulation; 6) in some cases, skin irritation from adhesives on surface electrodes; 7) breakage of the wire electrodes; 8) relatively greater risk of infection at the electrode site; and 9) early patient fatigue due to high energy demand from use of the device.

The second type of device is the percutaneous system, which is implanted into the body with leads and parts of the system remaining outside the body. In this case, only electrical impulses cross the skin. Percutaneous leads require surgery and have been designed as either intramuscular electrodes that are embedded into the fibers of the muscle or epimysial electrodes that lay on the surface of the muscle. This type of system can use an 8-channel implantable receiver/stimulator and an external control unit, which powers and instructs the radio frequency signals.⁶ Percutaneous interfaces require continuous attention from the user, and the electrode site must be cleaned, dressed, and properly maintained to avoid infection and possible breakage. Although these leads can remain functional for years without infection and complication, they are generally not considered preferable for long-term clinical use. The implantable system does offer an advantage by placing the stimulating electrode close to neural structures, thus greatly increasing selectivity and efficiency of activation while simultaneously reducing required current.⁷ Furthermore, the time required for donning and doffing of this system is relatively short, as it only requires connecting electrode leads to the stimulator/controller cables and the control sensors. None of these systems have received FDA approval.

The third type of system is a subcutaneous, fully implantable system, which includes both the stimulator and leads. These systems are in the early to-mid Phase II trials, but have not yet received FDA approval.⁸ These leads assume larger dimensions than percutaneous leads because they need to be more robust and resistant to failure. Some of the designs isolate the system subcomponents through high reliability, implantable connectors. These designs reduce the risk of infection and minimize the likelihood of damage to other implanted components. Fully implantable systems have overcome two of the key problems experienced with both the transcutaneous and percutaneous systems: (1) transcutaneous systems have difficulty in penetrating to deeper muscles, and (2) the wire electrodes of percutaneous systems have a history of breakage, as well as posing a relatively greater risk of infection at the electrode site than subcutaneous systems. The fully implantable systems may overcome these problems by implanting stimulation electrodes (as many as 16 channels) directly on the motor nerves and roots.⁹

Other technologies have also been used to enhance standing and walking in SCI patients. Some of these devices have been on the market for several years and are currently paid for by Medicare.¹⁰ They may include simple devices like ankle-foot-orthoses (AFO) or may be more complex such as bracing systems. Long leg braces are used to enhance standing and walking in spinal cord injured patients. Long leg brace systems can include custom hip-knee-ankle-foot orthoses (HKAFO), which couple the hip joints such that extension movement on one side is transmitted as flexion movement on the contralateral side (i.e., the reciprocating gate orthosis – RGO).¹¹ The disadvantage to these types of systems is that they are cumbersome and take time to put on and take off, and they may be cosmetically less appealing than NMES.

Food and Drug Administration (FDA) Approval/Clearance

Companies manufacturing neuromuscular electrical stimulators have obtained clearance for marketing of these devices under the FDA's 510(k) process for the following indications:

- Stroke rehabilitation by muscle re-education;
- Relaxation of muscle spasm;
- Prevention of retardation of disuse atrophy;
- Increasing local blood circulation;
- Muscle re-education and

- Maintaining or increasing range of motion.

There are numerous NMES devices cleared through the FDA for one or all of the above listed indications. However, devices that are used to enhance standing and walking by SCI patients raised different questions on safety and effectiveness than the predicate device. Therefore, the FDA required NMES devices for these indications to go through the more rigorous Premarket Approval Application (PMA) process.¹²

The Parastep®I system was classified by the FDA as a Class III device which did go through the PMA process. The Parastep®I system is the only NMES device that has been approved by the FDA for use by spinal cord injured patients for standing and walking. The FDA approved the product in 1994. The labeled indication is "to enable appropriately selected skeletally mature spinal cord injured persons (level C6-T12) to stand and to attain limited ambulation and/or take steps, with assistance if required, following a prescribed period of physical therapy training in conjunction with rehabilitation management of spinal cord injury...Effective use of the Parastep®I system requires the user to demonstrate 1) adequate trunk control and balance to maintain up-right posture while standing and ambulating, and 2) intact flexion withdrawal reflexes in the lower extremities to shorten adequately the limb to initiate taking a step." To ensure safety the patient must be able to stand with the assistance of a walker and safely lower himself/herself to the ground without the system operating or have assistance available in the event of device failure. All other NMES devices used to enhance standing and walking in SCI patients have not received FDA approval or clearance for marketing. Most of these devices have been developed by or in conjunction with academic centers conducting research on the use of these devices for SCI.

CMS assesses relevant health outcomes, above and beyond the safety/efficacy regulatory mandate of the FDA. Although a device must receive FDA approval or clearance for at least one indication to be eligible for Medicare coverage, except for a category B device under an investigational device exemption (IDE) clinical trial (60 FR 48417, September 19, 1995), FDA approval/clearance alone does not entitle that device to coverage. The device must fall under a Medicare benefit category and be determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member to be covered by CMS. CMS has the authority to conduct a separate assessment of a device's appropriateness for Medicare coverage, including whether it is reasonable and necessary specifically for its intended use for Medicare beneficiaries (see e.g., 60 FR 48417, 48420 (September 19, 1995)). Under a premarket approval application (PMA) review, as in the case of the Parastep®I, the FDA determines whether or not there is reasonable assurance of safety and effectiveness for the device's intended use that is stated in its proposed labeling. Medicare evidence-based national coverage determinations (NCDs) consider the medical benefit and clinical utility of an item or service in determining whether the item or service is considered reasonable and necessary under the Medicare program. CMS determines whether or not the device is clinically effective, i.e., does the technology improve net health outcomes in the Medicare population. Thus, FDA PMA approval by itself is not sufficient for making a determination concerning Medicare coverage.

The same applies to FDA 510(k) clearance. As we stated in 66 FR 58788, 58797 (November 23, 2001), "[t]he criteria the FDA uses in making determinations related to substantial equivalency under section 510(k) of the Food, Drug, and Cosmetic Act is significantly different from the scientific evidence we consider in making "reasonable and necessary" determinations under Medicare. FDA does not necessarily require clinical data or outcomes studies in making a determination of substantial equivalency for the purpose of device approval under section 510(k) of the Food, Drug, and Cosmetic Act. Medicare evidence-base NCDs consider medical benefit and clinical utility of an item or service in determining whether the item or service is considered reasonable and necessary under the Medicare program. Thus, a substantial equivalency approval under section 510(k) of FDA is not sufficient for making determination concerning Medicare coverage."

History of Medicare Coverage

In 1983, the Centers for Medicare and Medicaid Services (CMS)¹³ requested a technology assessment from the Office of Health Technology Assessment (OHTA) at the Public Health Service on the use of NMES in the treatment of muscle disuse atrophy in the absence of nervous system involvement. This assessment was limited to NMES use in clinical cases where neural supply (including brain, spinal cord and peripheral nerves) to the muscle is intact or where other non-neurological reasons for disuse are causing atrophy. The report excluded clinical situations where the cause of the disuse was considered permanent or was characterized by a non-reversible pathology. Based upon their complete assessment of all relevant literature, OHTA concluded that the use of NMES for the treatment of disuse atrophy is considered effective therapy where the cause of the muscle disuse is not permanent and there is no nervous system involvement. In this situation the treatment of disuse atrophy was considered a surrogate health outcome (that is, an intermediate outcome as opposed to an eventual outcome, such as the ability to ambulate), since the treatment of disuse atrophy generally leads to a full recovery of function.

Based upon the recommendations from the technology assessment, CMS issued a positive national coverage determination on the use of NMES for the treatment of disuse atrophy where the nerve supply to the muscle is intact, including brain, spinal cord and peripheral nerves, and where other non-neurological reasons for disuse are causing atrophy, all other uses of NMES were non-covered.¹⁴ This policy was established for use of NMES in various settings. The device could be used in an outpatient setting as a part of physical therapy services or in the home setting under the durable medical equipment benefit. This policy has been in effect since November 25, 1984.

This issue was re-examined by the CMS Technology Advisory Committee (TAC) in November 1990. The TAC, which included physicians employed by the federal government and CMS Contractor Medical Directors, assessed the issue of the use of NMES in the treatment of disuse atrophy for patients with permanent nervous system involvement. The panel reviewed several reports, which suggested that electrical stimulation may have a positive effect on muscular and cardiovascular functioning with respect to gait stability, reduction of pressure atrophy and a reduction in joint contractures for those patients who do not have an intact nervous system. However, the panel noted that there was a lack of conclusive evidence regarding the clinical benefit when using NMES to treat muscle atrophy for patients with permanent nervous system involvement. Therefore, the panel recommended that CMS ask the OHTA to conduct a full assessment of this issue.

Based on the panel's recommendation, CMS requested a technology assessment in November 1990. OHTA concluded in a brief report prepared in January 1991 that there is insufficient data to warrant a formal review of this matter. In their brief report OHTA concluded, "there is insufficient objective evidence of clinical effectiveness of NMES to conclude that the technology has identifiable, demonstrated medical benefits in patients with non-intact innervation of the muscle." OHTA found no published objective data supporting the benefit of NMES in improving circulation, preventing thromboembolic disease, reducing edema or preventing osteoporosis in patients with disuse atrophy and nervous system involvement.

The OHTA report also identified a body of evidence regarding the use of NMES by SCI patients to affect motor activities of daily living. Although the OHTA report noted that the investigators of the studies reported some success in utilizing this technology, these same investigators concluded that the technology has not yet been demonstrated to be of clinical significance and has rarely been successful outside the research setting.

In May 2002, after it was brought to our attention that several more recent studies have been conducted utilizing NMES on SCI patients, CMS internally generated a reconsideration of its national policy to look at NMES to enhance standing and walking.

Benefit Category Determination

In order for an item or service to be covered by the Medicare program, it must fall under one of the statutorily defined benefit categories, which are outlined in the Social Security Act. NMES meets the criteria to be classified under two different benefit categories. NMES does meet the definition of durable medical equipment (DME) under §1861(n) of the Social Security Act, and as outlined in Section 2100.1 of the Medicare Carrier Manual (MCM) and 42 CFR 414.202. Although, this device is considered DME, if the device is used solely for exercise in the patient's home, and used for a non-medical purpose it would not fall under any statutorily defined benefit category and could not be covered by Medicare. NMES also meets the definition of physical therapy services under §1861(s)(2)(D) of the Social Security Act.

Summary of Evidence

Literature Search Strategy and Review Criteria

A literature review was undertaken by CMS staff, which addressed the following outcomes-related primary questions:

1. Does NMES provide additional walking benefits in SCI patients above and beyond the baseline without therapeutic interventions?

2. Does NMES provide additional walking benefits in SCI patients above and beyond those realized with orthotic devices?
3. Does NMES offer any clinical benefits with respect to muscle disuse atrophy?

Several independent MEDLINE searches (limiting to human and English language studies, conducted 1985 - April 2002) were conducted to maximize the yield of potential articles in addressing the three above primary outcomes questions:

1. "electrical stimulation" and "neuromuscular" and "spinal"
 2. "electric stimulation therapy" and "spinal cord injuries" and "gait"
 3. "electrical stimulation" and "muscle atrophy" and "spinal cord injury"
-
3. "electric stimulation therapy" and "bone mineral density"

Additional sources of articles included the bibliography from a recent technology assessment by Hayes, Inc.,¹⁵ along with retrieving additional references from key articles. As a follow-up to the Web posting on this issue, CMS also received articles from the supporters of this technology. Product-specific clinical information on the Parastep®I system was obtained from both the FDA's Summary of Safety and Effectiveness Data and the transcripts of the FDA Orthopedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee, dated August 19, 1993.

Additional references from the most recent article on bone mineral density (BMD) were used to supplement the search on this area.¹⁶ After excluding case reports, review articles and studies that did not pertain to the above three questions, 26 studies (with 23 being case series) were read and abstracted into evidence tables. Since there was only one study with primary data on muscle disuse atrophy, two review articles were obtained in order to provide supplementary information. Table I includes those studies on the Parastep®I system, Table II includes studies from non-FDA approved NMES systems for standing and walking, and Table III includes studies on additional outcomes, including muscle atrophy, BMD and limb blood flow. Information available from the FDA was not abstracted since it was only available to CMS in either a summary or a transcript-based format.

The following secondary question was also formulated:

How often and for what duration has NMES been utilized in the home setting, after the completion of supervised training?

For this information, the above accessed literature was used, and no additional searching was performed.¹

Study Findings

Does NMES provide additional walking performance in SCI patients above and beyond the baseline without therapeutic interventions?

Phase II effectiveness data submitted to the FDA for the Parastep®I system¹⁷ included 67 spinal cord patients, recruited from 13 centers during the period November 2, 1990 through May 31, 1992, who had either complete thoracic paraplegia at T12 or higher (79%), incomplete thoracic paraplegia (18%) or incomplete cervical quadriplegia below C6 (3%). Both the age range (8 to 49) and gender ratio of 75% male/25% female are consistent with the prevalence pattern of SCI in young adults. Key inclusion criteria¹⁸ included patients having intact lower motor neurons (L1 and below), being at least six months removed from the injury or restorative surgery, and having sufficient upper extremity strength to properly use the device.

There was incomplete compliance with the 30-session training program required under the study protocol, with 26/67 patients (39%) completing the full program. This relatively low rate of compliance raises issues as to how well these devices may be used in less-structured, unsupervised settings. Twenty-two (22) patients (33%) were discharged from the NMES program for various reasons (i.e., 5 moved, 6 had time conflicts, 6 failed to follow the protocol, 4 had musculoskeletal problems unrelated to the Parastep®I system, and 1 patient failed to make progress). The remaining 19 patients (28%) remained active users of NMES, but had completed fewer than the full complement of 30 training sessions for reasons not specified. Ambulatory status data is provided below for each of the above three categories:

	> 30 Training Sessions		< 30 Training Sessions				
				Active		Discharged	
Ambulatory Status	No.	%		No.	%	No.	%
Independent	17	65		1	5	2	9
Verbal Assistance	1	4		1	5	0	0
Physical Assistance	8	31		16	85	13	59
Non-Ambulatory	0	0		1	5	7	32
Totals	26	100		19	100	22	100

This multi-center Phase II data was preceded by a Phase I developmental program at Humana-Michael Reese Hospital, with 18 patients having a similar demographic/injury profile to that listed above. All patients achieved standing and were able to walk at least 5 steps, with 12/18 (67%) walking 30 or more steps. Transcripts from the FDA Advisory Committee did not describe additional quantitative data on ambulation.

The FDA also requested a small study, which was conducted in July 1993 at the University of Texas – Southwestern Medical Center in Dallas. Five volunteer subjects (four male) with complete thoracic level injuries between T4-T12 who were experienced with the Parastep®I system (range 1-2 years) used it daily to weekly and had a mean age of 26.2 years (20-37). Ambulation attempts were videotaped for three activities, with double-masking (i.e., to the subject and physical therapist) in the latter two.

1. Unassisted ambulation attempt without use of Parastep®I system;
2. Ambulation attempt assisted with active Parastep®I system; and
3. Ambulation attempt assisted with inactive (placebo) Parastep®I system.

The following results were reported from this experiment:

1. All subjects were independent in coming to a standing position from a sitting position, with or without the active/inactive Parastep®I system;
2. No subject could ambulate without the active Parastep®I system or with the placebo system that did not deliver current to the lower extremity musculature;
3. All subjects required assistance to return to sitting in the wheelchair without the active Parastep®I system, and
4. All subjects ambulated independently with the active Parastep®I system.

Furthermore, gait efficiency was reportedly measured via temporal distance parameters, but actual data was not furnished in the study summary.

Several non-controlled, case series studies have addressed this question, and the inherent flaws with such study designs will be described in the ensuing section in greater detail. The largest study was conducted by Chaplin,¹⁹ who reported standing and ambulation performance data (along with training compliance data) among the first 100 patients evaluated for use of the Parastep®I system, without quantifying additional types of outcomes. Using very similar inclusion/exclusion criteria to the above FDA study of 67 patients, 91/100 such patients were deemed to be candidates for the system. Eighty-four patients (92%) were able to take steps, and 31 (34%) were eventually able to ambulate without the assistance of another person.

There are additional much smaller case series involving ambulation performance with the Parastep®I system (Table I). All studies have similar inclusion/exclusion criteria to the FDA effectiveness data set, involving young males with mainly complete thoracic paraplegia. Brissot *et al.*²⁰ reported that 13/15 patients acquired independent ambulation, with the other two withdrawing from the study. In spite of such gains, however, the study concluded that the high ratio of energy cost to effectiveness (speed) is likely to account for its limited use in daily activities.

Winchester et al.²¹ found that five Parastep®I users performed at significantly different levels, with even the best users being slower and less energy efficient than normal walkers. In a series of 16 subjects, Klose et al.²² revealed statistically significant overall differences across an 11-week study with respect to distance, duration and pace, noting that most of the peak values occurred in weeks 10 or 11.

Additional case series have reported performance data for non-FDA approved NMES ambulation systems. Wieler et al.²³ used 1-4 channel surface stimulation in 31 incomplete SCI patients from four Canadian centers and reported a 55% increase in walking speed, although a significant training effect was noted. Heller et al.²⁴ provided quantitative data on 3 subjects with complete SCI, who used an 8-channel surface stimulator, and the following ambulatory parameters were measured: distance walked (range 43.3-55.5 m), speed (range 0.30-0.40 m/sec, or 20-25% of normal speed), stride length (range 1.08-1.26 m) and stride time (range 2.97-3.60 sec). It may be assumed that such parameters were zero in the baseline period, given that no prior walking was noted among these subjects. Stein et al.²⁵ used 1-4 channel systems, with either surface, percutaneous or implanted electrodes in 10 subjects with incomplete SCI extending as high as C2. Stimulation increased the speed of ambulation in all subjects, with the mean difference being 4 m/min, independent of the speed at which the subject could walk without NMES (i.e., 4/10 patients were unable to walk without NMES). Ladouceur²⁶ demonstrated an increase in maximal over ground walking speed in 14 incomplete SCI subjects who were using walkers, forearm crutches or canes at baseline.

Does NMES provide additional walking performance in SCI patients above and beyond those realized with orthotic devices?

Although NMES may enhance standing and walking compared to no treatment, an important consideration is whether or not NMES is at least as good as technologies already covered by Medicare. Different types of orthotic devices enable standing and walking among SCI patients, and several case series studies have compared performance of NMES with such devices. Furthermore, some configurations have involved hybrid orthotic and NMES systems. Solomonow et al.²⁷ performed an evaluation of a hybrid device that used a reciprocating gait orthosis powered with NMES (RGO II) on 70 patients, who comprised a broad cross-section of the paraplegic population. Various standing and walking activities (i.e., donning and doffing the system; standing up and sitting down; walking on grass, gravel, ramps and up/down curbs and walking at least 180 meters) were assessed by level of injury. There were relatively greater success rates in performing these activities among patients with lower vs. upper SCI.

Granat et al.²⁸ studied six patients with incomplete SCI and compared walking speeds in patients using orthoses (unspecified types) vs. surface NMES (Strathclyde programmable stimulator). Differences were not significant, and neither group achieved gait speeds comparable with normal walking. Thoumie et al.²⁹ also used the RGO II hybrid orthosis, where the study design allowed for the variable use of NMES. Without NMES, the maximum walking distance range was 150-400 m, and with NMES, it was 200-1400 m, but no detailed statistical comparisons were available. There were no significant differences in walking speeds, and both remained 15-20% of normal walking speed. Survey data reported by Maxwell et al.³⁰ received from 1,122 SCI individuals, demonstrated that orthotic users (i.e., AFO) had superior walking performance, but this may have been offset by the fact that such subjects tended to have motor incomplete injury relative to the NMES subjects who had motor complete injury. Marsolais et al.³¹ evaluated six subjects, without prior exposure to NMES, who were assessed both without and with NMES. All patients showed at least qualitative ambulation performance improvements, using RGO plus NMES vs. RGO alone, with one of the four patients demonstrating increased measured distance (from 3 to 350 m).

Bonaroti *et al.*³² compared long leg bracing orthotics (i.e., knee-ankle-foot braces in four pediatric patients and an RGO in a fifth pediatric patient) and subcutaneous NMES in a study, which assessed eight activities: Donning, stand and reach, high transfer, floor to stand, six-meter level ambulation, toilet transfer, stair ascent (in standing) and stair descent (in standing). A direct paired comparison of these eight measures among each of the five subjects showed that NMES required equal (70%) or less (24%) assistance than orthosis, with orthosis necessitating a lower level of assistance for the remaining 6% (i.e., one patient for floor to stand and another patient for a six-meter walk). Levels of assistance were categorized using a general scoring method for the functional independence measure (FIM), where a score of 1 represents total assistance, and 7 denotes complete independence. Furthermore, utilizing a separate measurement of group average time-to-completion, 2/8 activities (i.e., stand and reach and high transfer) were performed faster with NMES.

Does NMES offer any clinical benefits with respect to muscle disuse atrophy?

Few studies addressing the question were identified in our literature search. Baldi *et al.*³³ reported that NMES cycle ergometry prevented muscle atrophy in acute SCI after three months of training, and caused increased mass after six months of training. This trial used a controlled study design in which 26 subjects, 14-15 weeks post-traumatic SCI, were assigned to three groups: Control group, an NMES isometric exercise group and an NMES cycle ergometry exercise group. Lean body (muscle) mass was calculated in each group using dual energy X-ray absorptiometry (DEXA). The setting of NMES use differed considerably from other studies in that acute, rather than chronic, SCI subjects were recruited.

A 1994 review article by Gordon and Mao³⁴ could not reference any study data on the treatment of muscle atrophy by NMES in SCI patients, and a more recent 2001 review article on exercise by Jacobs and Nash³⁵ mentioned two studies in which the "chronic administration of electrical current to knee extensors using resistance placed at the ankle reportedly increases muscle mass and girth for individuals with complete upper motor neuron lesions." However, increased muscle mass does not necessarily mean that the patient experiences an improved health outcome. Unlike neurologically intact patients in whom treatment of disuse of atrophy with NMES leads to a full recovery, SCI patients do not experience a full recovery. Therefore, we reviewed studies that evaluated the effect of NMES on potential health outcomes or surrogate measures for treating disuse atrophy in SCI patients.

Bone mineral density (BMD) is a potentially relevant surrogate outcome since there is a well-described relationship between low BMD and a higher risk of fractures,³⁶ and treatment of disuse atrophy with NMES theoretically could lead to increased BMD. There is conflicting data on NMES and BMD, which have been evaluated as part of structured cycling and isometric exercise programs, using NMES configurations, which differ than those, employed for ambulation. Needham-Schropshire *et al.*,³⁷ in a continuation of studying the same patients as Klose *et al.* (2000) at the University of Miami, were unable to find any significant changes in BMD after approximately 12-20 weeks of training with the Parastep®I system. Similar negative findings were found several years earlier by Leeds *et al.*³⁸ at the University of Miami using NMES cycle ergometry. Although DeBell *et al.*³⁹ could not find significant BMD improvement with such NMES lower extremity cycling, there was a positive trend in the lumbar spine.

On the other hand, Bloomfield *et al.*⁴⁰ reported a significant improvement using NMES cycle ergometry in the lumbar spine for nine paraplegic and quadriplegic patients, using a non-randomized case-control design. Finally, Belanger *et al.*⁴¹ reported a 28.7% recovery of lost BMD in the distal femur and 28.0% recovery in the proximal tibia, comparing 14 SCI patients with 14 volunteer age and sex-matched controls without randomization. The method of training involved both anti-gravity and added resistance maneuvers in the lower extremities.

No studies have been performed comparing the effect of orthotics and NMES on BMD.

How often and for what duration has NMES been utilized in the home setting, after the completion of supervised training?

Brissot *et al.*⁴² noted that 5/13 patients continued using the device at home for physical fitness (as of the time at publication), but none for ambulation; however, actual durations were not provided. Chaplin⁴³ presented a subset of 48/91 subjects, 75% of whom used the Parastep®I system three or more times per week, but duration of use was also not addressed. In the six-patient series by Granat *et al.* above, using a mean follow-up of 12 months after completion of the program, 3/6 patients continued to use their NMES system at home, discarding their original orthoses, and the other 3/6 patients discontinued use of NMES after finding it impractical. Once again, there were not sufficient details on actual duration of use.

Gallien *et al.*⁴⁴ followed eight patients who possessed their own Parastep®I system over a mean follow-up period of 15 months. Although average duration of use could not be calculated, 4/8 continued to use the device (at the time of publication), with one patient noted to have 2.5 years of home use. Wieler *et al.*⁴⁵ reported that 23/40 (58%) of patients who underwent initial supervised testing with NMES decided to use it on a continuing basis although the study follow-up period was not available. Out of 26 patients in the series by Thoumie *et al.*⁴⁶, 4 patients continued to use an RGO-II hybrid orthosis in "protected areas" such as the rehabilitation center, 11 patients used their orthoses at home and 6 patients stopped using their orthoses as soon as they returned home. However, no duration data was available.

Solomonow *et al.* above reported upon 41 patients, who participated in a discharge survey: 22% used the hybrid RGO system more than 3 times per week, 27% used it 1-3 times per week, 12% used it one or more times per month, and 20% were non-users. There was no specific follow-up period reported for this discharge survey profile. Additional quantitative data on the use of NMES were provided by Sykes *et al.*⁴⁷ Both electronic step counter and diary data were used to assess an RGO, with and without NMES, and there was no trend to demonstrate increased use following supply of the hybrid system. Diary data showed similar low use (i.e., often less than one hour per day) with and without NMES during the 18-month evaluation period. A less well-quantified report from Moynahan *et al.*⁴⁸ revealed that subjects overwhelmingly declined to wear an NMES system all day, but frequency data on days used for exercise revealed that 4/5 patients continued using the system, in some capacity, for at least 300 days. Furthermore, by having to respond to regular questioning about their use of the NMES system, subjects admitted that they sometimes felt compelled to increase what they perceived as an infrequent pattern of use because they were in the study. Finally, Davis *et al.*⁴⁹ showed mixed usability/preference scale results for NMES vs. conventional transfers, such that the potential advantages of one approach over the other could not be evaluated.

Position Statements - We checked with several groups, such as the American Academy of Physical Medicine and Rehabilitation, and could not find any organization that had a position statement on this matter. We talked with clinical experts from the Functional Electrical Stimulation Center in Cleveland, along with specialists from the National Institutes of Health and Northwestern University.

Correspondence - We received 11 letters in support of the use of NMES in SCI. We received letters from the Functional Electrical Stimulation Center in Cleveland, the Miami Project to Cure Paralysis, the manufacturer of the Parastep®I system, individual practitioners and patients. In addition to letters of support, we received numerous scientific articles. Some of the articles met our review criteria and were included in this analysis. Our critique of articles that we identified for our analysis, as well as articles and comments submitted by the public, are addressed in the CMS Analysis section of this document. Several of the letters we received were from researchers using the Parastep®I system. These letters provide anecdotal information on the health benefits from using this system. We also received letters of support from researchers using an implantable system.

CMS Analysis

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act. §1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." §1862(a)(1)(A).

When making national coverage decisions, we evaluate relevant trials to determine whether or not the data is of sufficient quality to support a finding of clinical effectiveness. CMS considers several generally accepted methodological principles when assessing a clinical trial. For example, we evaluate whether or not general methods of study design have been followed, such as calculating sample size *a priori*, specifying inclusion and exclusion criteria, describing the process for the selection of study participants and the ways in which the consistency of this process was maintained, ensuring comparability of experimental groups at baseline to the extent possible, describing baseline characteristics of the participants, randomizing study subjects, masking of patients and investigators to the therapy administered to the extent feasible, describing co-interventions in detail, and performing appropriate statistical analyses, such as statistical tests of differences in baseline characteristics between the comparison groups. CMS evaluates other study design issues, which, in the case of physical therapy intervention trials, include, among other things, the following:

- Has an appropriate outcome been used?
- Have appropriate measures of endpoints been selected, identified prior to initiating the trial, and standardized across all study sites?
- Have clear measurement criteria been provided? Has the process used to measure the selected outcomes and methods in which the study investigators insured the consistency of this process across different study sites been described?
- Was the appropriate patient population studied?
- Have all subjects, regardless of the protocol arm to which they are assigned (e.g., investigational treatment, control), received good standard therapy and the same standard therapy procedures? Have the standard therapy procedures been described in detail?
- Have adequate follow-up evaluations been performed? Clinical benefits from therapies can be short-lived and, therefore, of limited clinical value.

In order to properly evaluate the contribution of NMES to improved health outcomes, there needs to be both a delineation of what outcomes are appropriate, as well as pertinent study designs to report upon such outcomes. Although randomized controlled trials, with appropriate masking, are most desirable, such controlled trials are admittedly not feasible in situations where it is known *a priori* that subjects not receiving any intervention (in this case, SCI patients) have an intrinsic disadvantage to those receiving a potentially promising intervention. However, randomized controlled clinical trials can compare different interventions such as NMES vs. orthotics (e.g., bracing systems), even if it remains impractical to include all preferred design features such as masking of both patients and investigators to the specific intervention. The case series design is inherently limited since one cannot ensure that the intervention itself results in specific outcomes, relative to other extraneous factors, without control or comparative groups to account for the potential influence of such other variables upon outcomes.

All the case series studies performed using NMES are flawed due to study design issues such as the failure to use appropriate control or comparison groups, lack of randomization, small sample size and/or inadequate outcome measures that may have led to the introduction of bias. Therefore, the studies may have reported positive findings that were not due to NMES.

In this evaluation of SCI patients, an important consideration is the ability to ambulate as compared to other technologies already covered by Medicare. The ability to stand, in the absence of ambulation, has not been considered a benchmark of clinical utility with respect to NMES, particularly where patients eligible for use of NMES (both under the FDA labeling for Parastep®I and in most clinical trials) must be able to stand with a walker without using NMES. In spite of serious flaws, the case series evidence summarized in the previous section makes a satisfactory case that NMES is superior to no interventions with respect to the ability of SCI patients to ambulate. Although most of the above studies had a mixture of data from patients with complete SCI (where pre-interventional ambulation was not possible) and incomplete SCI (where some ambulation was possible), there were a sufficient number of patients who were able to ambulate purely as a result of NMES.

The evidence does not demonstrate that NMES confers such walking performance advantages over alternative assist devices such as orthotics, since there are no robustly designed studies to effectively compare these technologies. However, the literature suggests at least equivalence between the two technologies for walking. With respect to hybrid orthoses, the studies by Thoumie and Marsolais above suggest walking performance enhancement with the addition of NMES to orthotics. Nevertheless, both small studies suffer from poor quantitation of results, which do not allow for any inferences to be made regarding the net benefits conferred by such a hybrid approach. Therefore, the evidence is adequate to conclude that NMES is clinically effective and, thus, reasonable and necessary for walking in SCI patients. However, because the scientific literature demonstrates infrequent use of NMES and insufficient information on the duration of continued use at home for walking, coverage will be limited to those SCI patients who continue to use the device after a reasonable trial period.

Although the literature (e.g., Baldi *et al.* above) suggests that NMES may increase muscle mass in some SCI patients with disuse atrophy, the literature does not demonstrate that this use for NMES leads to improved health outcomes (as compared to neurologically intact patients), such as the reduced risk of fractures from increased bone mineral density. The BMD studies had methodological limitations and provided mixed results with respect to the effects of NMES. Therefore, the literature does not support a significant effect on BMD, and thus a reduction in risk of fractures, from the use of NMES. Limb blood flow is another surrogate physiological outcome, which has been shown to increase via NMES by Nash *et al.*,⁵⁰ although the authors used uncontrolled data, which limits the validity of their findings. However, limb blood flow is not an adequate surrogate measure, because it has not been clearly linked with a health outcome. Therefore, the evidence is not adequate to conclude that NMES is clinically effective for the treatment of disuse atrophy in SCI patients. Thus, NMES is not reasonable and necessary for this indication.

In summary, the evidence is adequate to conclude that the use of NMES in SCI patients for walking is clinically effective. The comparison of NMES with conventional orthotics indicates that there is at least equivalent performance of these alternative approaches. However, no such evidence is available to support NMES in the treatment of muscle disuse atrophy for SCI patients. In the future, CMS encourages interested parties to undertake appropriately controlled studies which can more fully demonstrate the clinical utility of NMES. For example, Moynahan *et al.*, described above, poses some key research initiatives, which are relevant to addressing this matter:

1. Compare the capabilities of subjects performing a standard set of activities using a wheelchair, orthotics and NMES.
2. Elucidate both the mobility needs of SCI subjects and the ability of an NMES system to meet these needs.

It is not possible, given such sparse data, to address technical differences among NMES devices (e.g., intramuscular vs. surface electrodes) with respect to their potential effects upon walking. The newer types of implantable NMES devices may reduce many of the problems reported with other types of systems, such as percutaneous devices, but these devices generally are still in the early testing phases. The NMES literature is also characterized by multiple "home-brew," non-FDA cleared/approved devices which have been used at study sites only, but it is not possible to determine if similar results would be obtained in other settings. As a general matter, Medicare does not cover FDA-regulated devices that the FDA has not approved, cleared or exempted from premarket review for at least one indication.

DECISION:

One type of NMES that is used to enhance functional activity of spinal cord injured (SCI) patients is commonly referred to as functional electrical stimulation (FES). These devices use electrical impulses to activate paralyzed or weak muscles in precise sequence and have been utilized to provide SCI patients with the ability to walk. Based on all of the evidence that we have reviewed, it is our intention to issue a positive national coverage determination for the use of NMES/FES limited to walking in SCI patients, but we will maintain the existing national non-coverage policy for the treatment of disuse atrophy in SCI patients. Use of NMES/FES poses a risk from falling for SCI patients. It also requires that a person possess certain abilities to successfully use these types of devices. In addition, patients require many sessions of physical therapy to learn how to use the device properly and the clinical studies report that many patients do not use NMES/FES long term. Therefore, we will cover an NMES/FES system when used by an SCI patient for walking in the home only after the patient has completed regular sessions of physical therapy with the device over a period of 3 months. This trial period of physical therapy will enable the clinician to properly evaluate the person's ability to use these devices for the long term.

The goal of this therapy must be to train SCI patients on the use of NMES/FES devices to achieve walking, not to reverse or retard muscle atrophy. The training program would be covered under the physician fee schedule, with no additional payment being made for the equipment used by the patient, as the equipment is in the practice expense portion of the payment.

Consistent with the FDA labeling for Parastep®I and the inclusion criteria for most of the studies reviewed, coverage for NMES/FES for walking, whether in the setting of physical therapy or home use, will be limited to SCI patients with all of the following characteristics:

- 1) persons with intact lower motor units (L1 and below);
- 2) persons with muscle and joint stability for weight bearing at upper and lower extremities that can demonstrate balance and control to maintain an upright support posture independently;
- 3) persons that demonstrate brisk muscle contraction to NMES and have sensory perception of electrical stimulation sufficient for muscle contraction;

4) persons that possess high motivation, commitment and cognitive ability to use such devices for walking;

5) persons that can transfer independently and can demonstrate standing tolerance for at least 3 minutes;

6) persons that can demonstrate hand and finger function to manipulate controls;

7) persons with at least 6-month post recovery spinal cord injury and restorative surgery;

8) persons without hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis; and

9) persons who have demonstrated a willingness to use the device long-term.

NMES/FES for walking will not be covered in SCI patients with any of the following:

- 1) persons with cardiac pacemakers;
- 2) severe scoliosis or severe osteoporosis;
- 3) skin disease or cancer at area of stimulation;
- 4) irreversible contracture; or
- 5) autonomic dysreflexia.

All uses of NMES other than for the treatment of disuse atrophy in neurologically intact patients and for walking in SCI patients remain non-covered.

1 Spinal Cord Injury: Facts and Figures at a Glance. (2002). Spinal Cord Injury Information Network. (WWW document). Retrieved: http://www.spinal_cord.uab.edu/show.asp?durki=21446

2 National Institutes of Health, National Institute of Neurological Disorders and Strokes, *Spinal Cord Injury-Emerging Concepts*, www.ninds.nih.gov/health_and_medical/pubs/sci_report.htm, 2000.

3 Graupe D, *et al.* 1998.

4 *ibid.*

5 Chae J, *et al.* 2000.

6 Marsolais EB, *et al.* 2000.

7 Chae J, *et al.* 2000.

8 There are four phases of clinical trials. Phase I studies are designed to establish the effects of a new product in humans and are usually conducted on a small population of healthy humans. Phase II studies are conducted after the successful completion of a Phase I study, and they are performed in a slightly larger population of individuals who are afflicted with the disease or condition. Phase III studies are conducted on a large population of afflicted individuals. These tests typically compare the new intervention with standard therapy currently being used to treat the disease. Phase IV studies occur after approval when the product has been dispersed to the public.

9 Chae J, *et al.* 2000.

10 Social Security Act §1861(s)(9).

11 Chae J, *et al.* 2000.

12 The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act (the act) established three regulatory classes for medical devices. The three classes are based on the degree of control necessary to assure that the various types of devices are safe and effective. The most regulated devices are Class III. The amendments define a Class III device as one that supports or sustains human life or is of substantial importance in preventing impairment of human health or presents a potential, unreasonable risk of illness or injury. Under Section 515 of the act, all devices placed into Class III are subject to premarket approval requirements. Premarket approval by FDA is the required process of scientific review to determine if a Class III device provides reasonable assurance of safety and effectiveness.

13 CMS formerly was the Health Care Financing Administration (HCFA).

14 Medicare Coverage Issues Manual, Section, 35-77.

15 Hayes Report

16 Belanger M, *et al.* (2000).

18 Inclusion criteria:

- a. Sex: Males and females of non-childbearing potential. Females of childbearing potential were eligible if they had a negative pregnancy test at the enrollment visit and were using adequate contraceptives;
- b. Age: 16 years and older;
- c. At least six months post recovery spinal cord injury and restorative surgery;
- d. Stable ortho-neuro-metabolic systems;
- e. Intact lower motor units (L1 and below);
- f. No history of long bone fractures secondary to osteoporosis;
- g. Without hip or knee degenerative joint disease;
- h. Patient demonstrated and expressed high motivation and commitment to the program;
- i. Muscle and joint stability was available for weight bearing at upper and lower extremities;
- j. Range of motion available at all extremity articulations;
- k. Patient demonstrated brisk muscle contractile response to neuromuscular electrical stimulation;
- l. Motor hyperactivity was sufficiently controlled to allow safe independent upright stance;
- m. Patient demonstrated cognitive ability to successfully employ the Parastep®I System;
- n. Sensory perception of electrical stimulus allowed for sufficient level required for muscular contraction;
- o. Patient was without orthostatic hypotension which would limit standing tolerance;
- p. Patient was independent in all transfers;
- q. Patient demonstrated standing tolerance greater than 3 minutes;
- r. Patient demonstrated balance and control skills to maintain an upright supported posture independently;
- s. Patient demonstrated hand and finger function to manipulate system controls;
- t. Patient was without skin disease, decubiti or dermatological condition at stimulation sites which prevented the application of electrodes;
- u. Upper extremity strength was sufficient for patient to lift his/her body weight out of a chair and into a standing walker;
- v. NMES muscle power was sufficient to maintain locked knees while full weight bearing in standing double support? (A grade of fair+ with NMES manual muscle testing);
- w. Standing posture erect with less than 20% of body weight born by the upper extremities; and
- x. Informed consent was signed by patient or legally authorized representative prior to administration of study treatment.

Exclusion criteria - Patients who met any of the following criteria were NOT eligible for enrollment:

- a. Cardiovascular disease or pulmonary insufficiency
- b. Epilepsy;
- c. Pregnancy;
- d. Severe scoliosis;
- e. Severe osteoporosis which precludes standing;
- f. Skin disease at stimulation sites;
- g. Irreversible contracture;
- h. Morbid obesity;
- i. Vision or hearing impairments which interfere with training;
- j. Frequent or severe autonomic dysreflexia; or
- k. Other: Any condition or circumstance which would prevent completion of study participation or interfere with analysis of study results, including the inability to attend to the training schedule.

19 Chaplin E, 1996.

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37 Needham-Shropshire BM, *et al.* 1997.

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46 Thoumie P, *et al.* 1995.

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